K111522

May 31, 2011

SEP 2 9 2011

510 (k) Summary

Proprietary Name: Chartis™ Catheter

Classification Name: Tube, tracheal/bronchial, differential ventilation (w/wo connector)
21 CFR 868.5740 Class II
Classification: CBI

Common Name: Tube, tracheal/bronchial, differential ventilation (w/wo connector)

Manufacturer: Pulmonx, Inc.
700 Chesapeake Drive
Redwood City, CA 94063
650-364-0400 (phone)
650-364-0403 (fax)

Contact: Rich Ferrick
VP, Regulatory Compliance and Quality Assurance

Preparation Date: May 31, 2011

Predicate Device:

The Chartis Catheter is substantially equivalent to the following currently marketed predicate device:

Chartis Catheter (K083883, cleared on June 25, 2009, product code CBI, regulation number 868.5740)

Device Description:

The Chartis™ Catheter is a single use, sterile, disposable device designed to be inserted into the working channel of a standard video or fiber bronchoscope during a diagnostic bronchoscopy procedure. After the target lung segment is accessed by the bronchoscope, the distal tip of the Chartis Catheter can be introduced through the bronchoscope directly into the target airway. Inflation of the compliant balloon on the distal tip of the Chartis Catheter causes the airway to become sealed and isolated. Air can then flow out of the isolated lung compartment into the environment only through the central lumen of the Chartis Catheter. Assessment is accomplished by measuring air flows and pressures exiting the Chartis Catheter lumen during spontaneous respiration.

Intended Use:

The Chartis System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is a re-useable piece of capital equipment that displays the patient information.

Technological Characteristics:

The modified Chartis Catheter is substantially equivalent to the predicate Chartis Catheter with regard to technological characteristics. The minor changes to materials, packaging, and shelf-life do not raise new types of safety or effectiveness questions..

Performance Data:

Verification and validation test results support the performance characteristics of the modified device and show equivalence to the currently marketed predicate device.

Conclusion:

The Chartis Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Hans Schulz
Director of Quality Assurance
Pulmonx, Incorporated
700 Chesapeake Drive
Redwood City, California 94063

SEP 29 2011

Re: K111522
Trade/Device Name: Chartis Catheter
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: August 29, 2011
Received: August 30, 2011

Dear Mr. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number Not known K111522

Device Name Chartis Catheter

Indications for Use The Chartis System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is a re-useable piece of capital equipment that displays the patient information.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per CFR 801.109)

(Division Sign-Off) 9/28/11
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111522